(12) UK Patent Application (19) GB (11) 2 370 778 (13) A

(43) Date of A Publication 10.07.2002

(21) Application No 0122999.6

(22) Date of Filing 25.09.2001

(30) Priority Data
(31) 0003432 (32) 26.09.2000 (33) SE

(51) INT CL[7]
A61B 19/00

(52) UK CL (Edition T)
A5R REYX

(56) Documents Cited
GB 2213066 A US 4617925 A
US 4350159 A

(58) Field of Search
UK CL (Edition T) A5R REYX
INT CL[7] A61B 17/00 19/00
WPI EPODOC PAJ

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(54) Abstract Title
Stereotactical Instrument

(57) A non-invasive stereotactical instrument for identifying the spatial position of an area in a patient's skull which is to be subjected to treatment. The instrument comprises a non-yielding frame (1), which is arranged to be supported by the patient's skull (6) and to support an indicating device (42) and/or a treatment instrument. A bite block (18) is movably attached to the frame and arranged to engage the upper teeth in the skull or the palate. At least one pair of interacting fixing means (27, 28) provided with a scale (49) are displaceably attached to the frame (1) and arranged to engage, by means of support elements (30), the skin of the occipital bone of the skull (6) in a non-invasive manner.

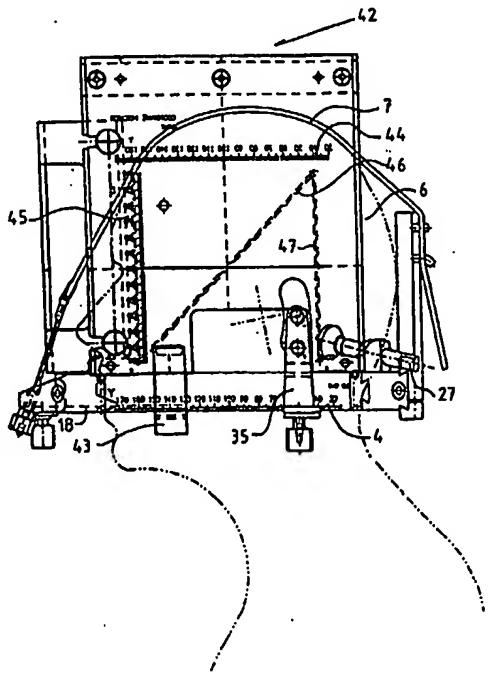

FIG 3

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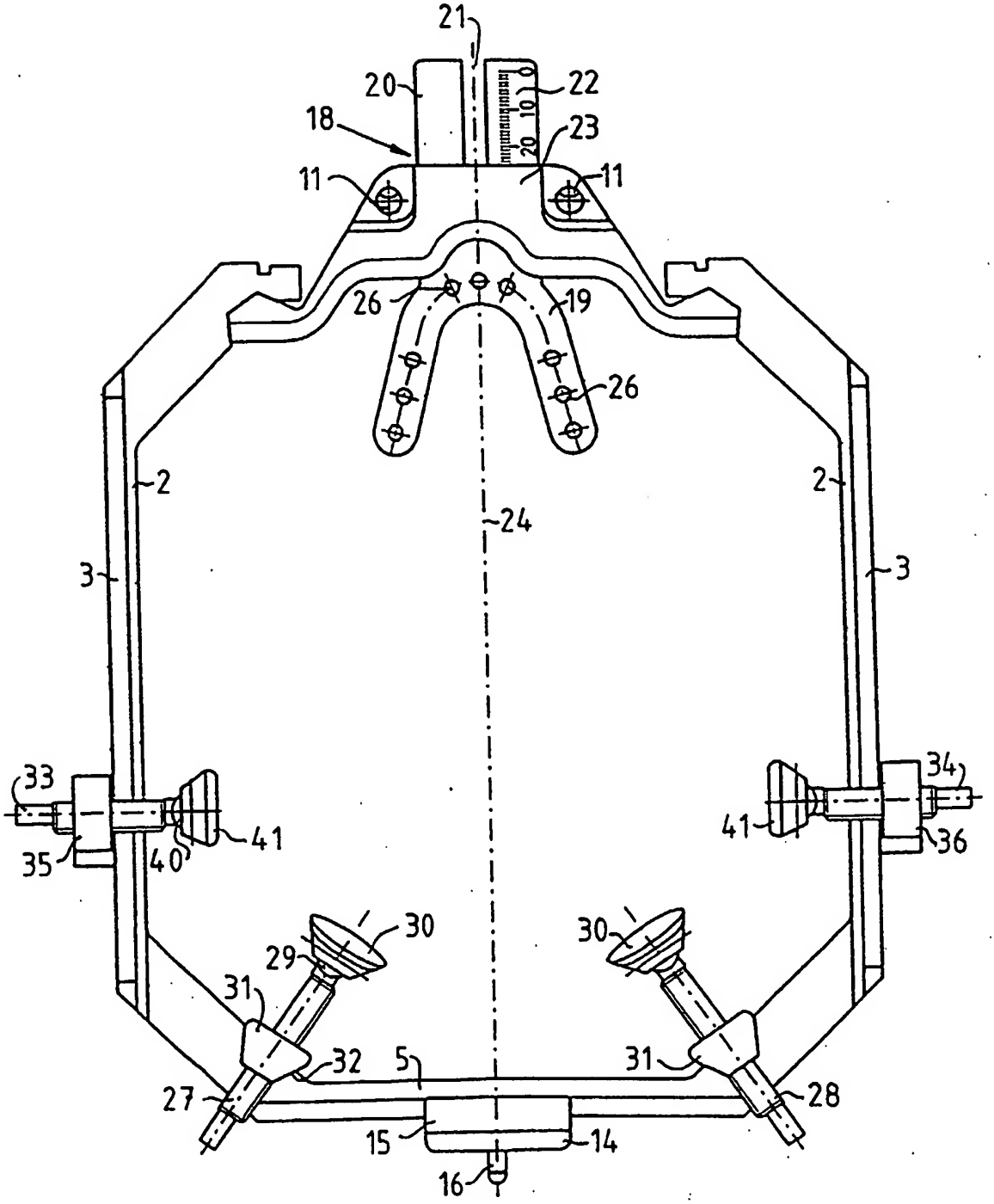
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FIG 1

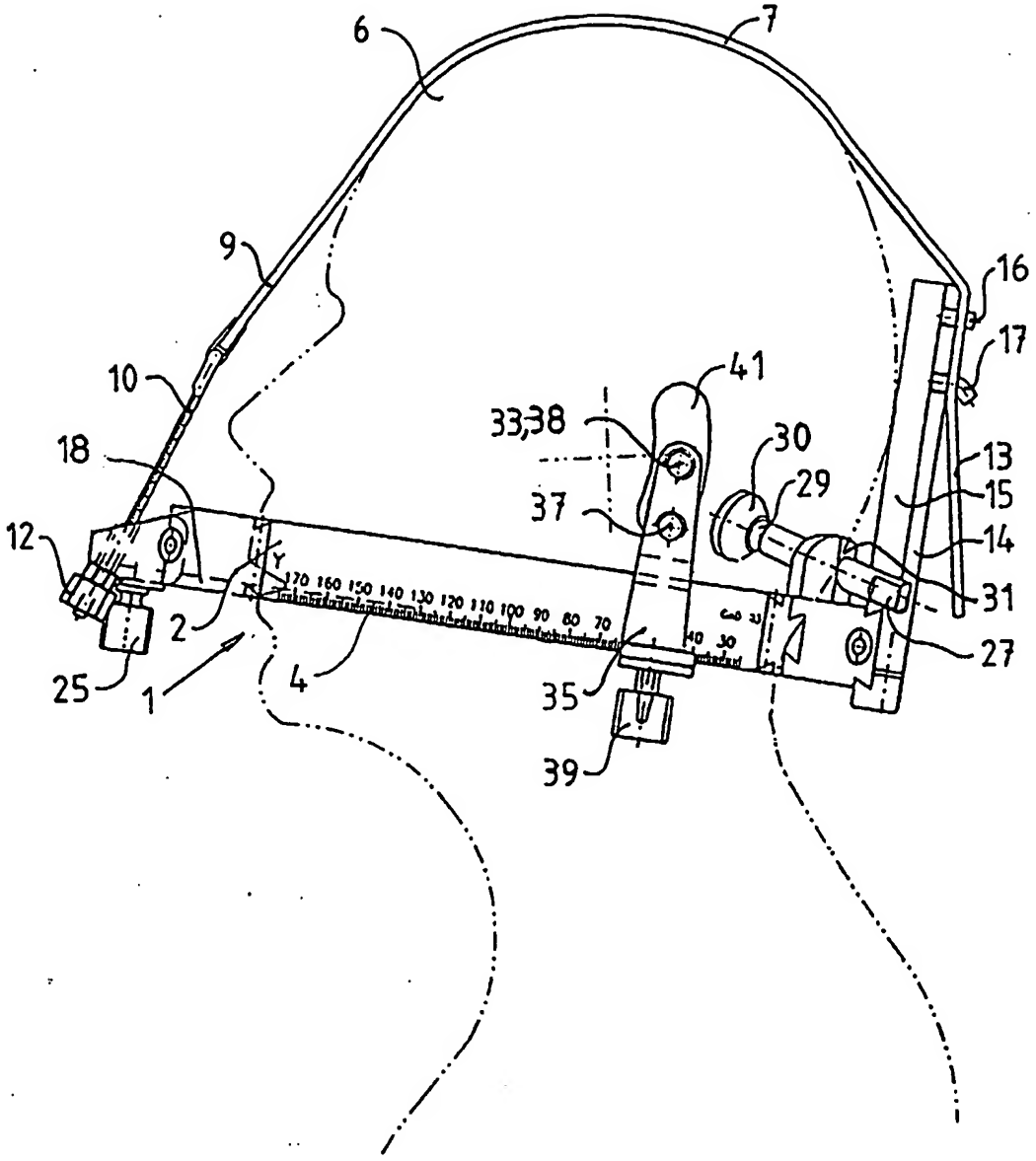

FIG 2

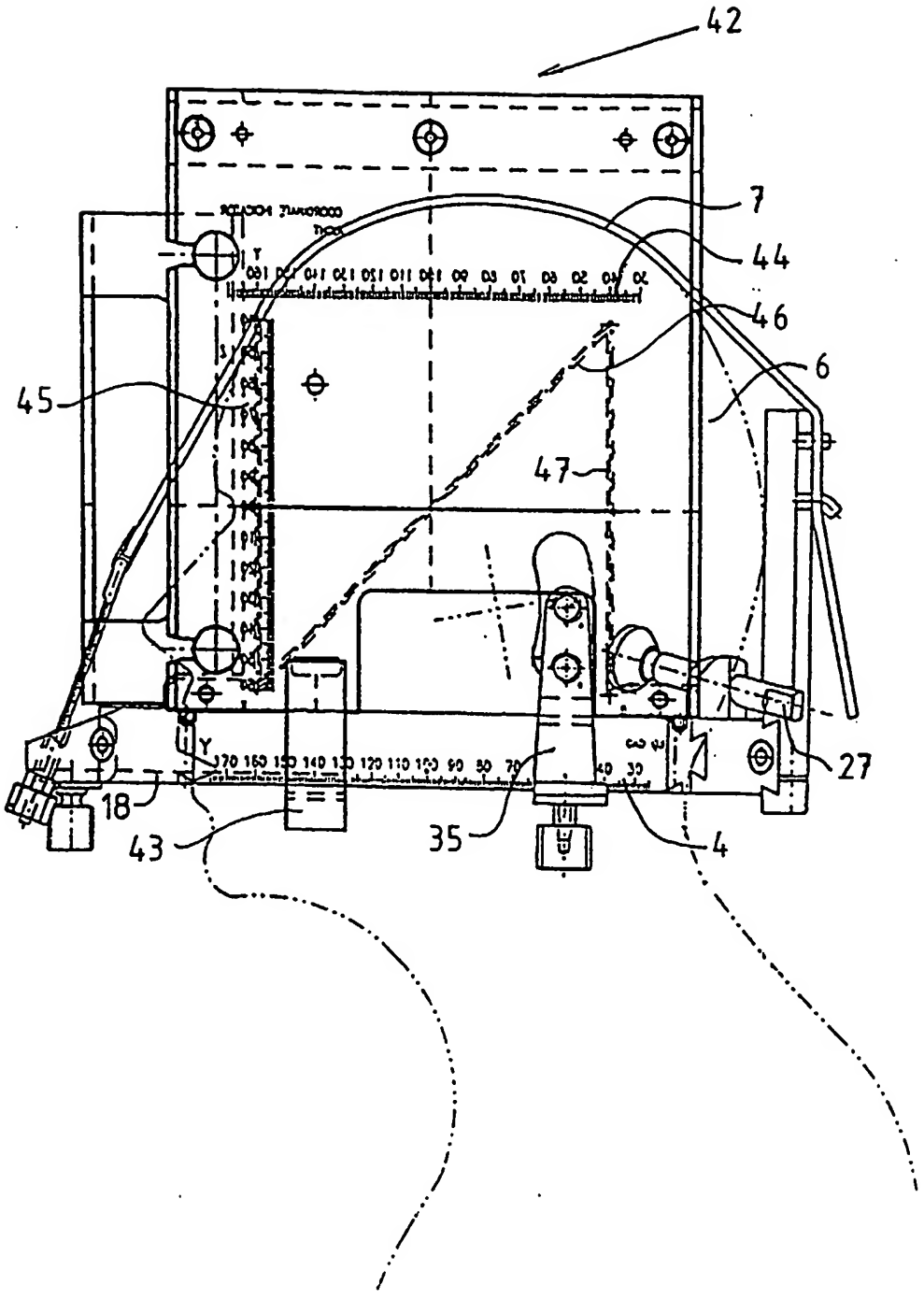

FIG 3

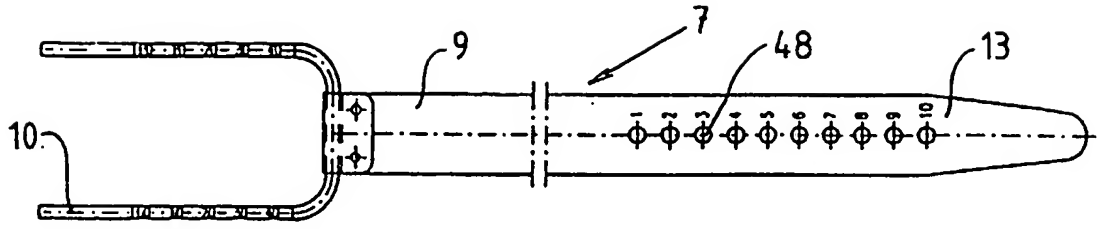

FIG 4

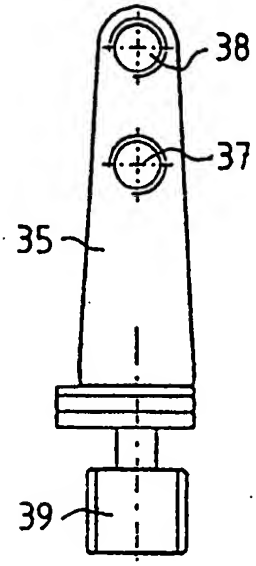

FIG 5A

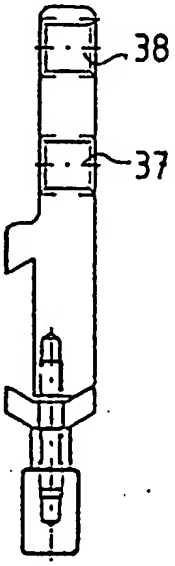

FIG 5 B

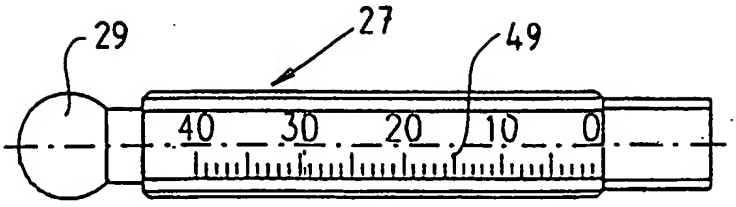

FIG 6A

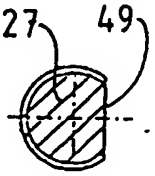

FIG 6B

STEREOTACTICAL INSTRUMENT

The present invention relates to a non-invasive stereotactical instrument for identifying the spatial position of an area in a patient's skull which is to be subjected to treatment, the position of the area being previously determined, for example by means of angiogram, PET, or X-ray equipment, the instrument comprising a non-yielding frame, which is arranged to be supported by the patient's skull and to support an indicating device and/or a treatment instrument, and fixing means, which are displaceably attached to the frame and which are arranged to engage the skull for repeatable fixing of the instrument relative to the skull.

In non-invasive (bloodless) treatment of the brain, such as radiation treatment or heat treatment, as well as in surgical operations on the skull, the possibility of identifying, with great accuracy, the position of the area(s) of the patient's skull which is/are to be treated is highly important. To minimise the risk of unnecessary brain damage arising as a result of the treatment, the surgeon must be sure of hitting, with reasonable accuracy, the correct area, without having to make unnecessary passages through sensitive tissue.

It is vital that the treatment area in the brain can be easily and safely identified on different occasions, particularly as regards non-invasive treatment, since radiation treatment, for example, requires a number of successive treatment sessions. As the patient is conscious during treatment, due to the fact that the treatment is painless and takes only a few minutes to perform, it is also essential that he or she experiences as little discomfort as possible during each treatment session.

International Patent Specification WO88/08282, which corresponds to US 5,116,344, discloses a stereotactical instrument according to the first paragraph of the

description. This instrument is also described in Elekta's brochure "Leksell Micro-stereotactic System", to which reference is hereby made. It here appears that the spatial position of the area which is to be treated is determined by means of angiogram, X-ray, PET, DSA, CT and/or MRI, a box or cage construction with scales being used, for example, to obtain the coordinates of the treatment area in the skull. For this purpose, said construction is attached to a non-yielding frame, which in turn is fixed to the skull with the aid of fixing means which are displaceably attached to the frame and arranged to penetrate the skin so as to be attached to the bone of the skull. The instrument is thus painful for the patient to carry, and it also causes bleeding. Therefore, it is intended for surgical operations where the patient has been given a local anaesthetic or has been anaesthetized, but is not suited for radiation treatment or the like, where it is not desirable that the patient should have to remain at the hospital for a number of treatments.

US 4,617,925 discloses a stereotactical instrument, which is arranged to be non-invasively attached to a patient's skull and fixed by means of earplugs and a nose root support. A patient can be fixed to an operating table or the like by means of a fixing device, which is connected to an instrument. The instrument is supported mainly by the earplugs, which is probably painful and unpleasant for the patient. The instrument will also hinder the surgeon, since the lowest portion of the instrument is located at the same level as the ears of the patient and several components of the instrument extend across the skull area.

US 4,350,159 discloses a stereotactical instrument having a non-yielding frame and skin-penetrating fixing means. The instrument has a plurality of adjustment mechanisms for alignment of, inter alia, the holders supporting the suspension device of the surgical instrument. This makes the instrument, besides being invasive, both heavy and complicated and expensive to manufacture.

An object of the present invention is thus to provide a stereotactical instrument, which is non-invasive, easy to apply and carry and thus not unpleasant for the patient and which permits safe and repeatable identification of the treatment area in the skull.

A further object of the invention is to provide a stereotactical instrument, which does not impede the performance of the treatment and which allows the patient to remain mobile relative to the treatment device.

Another object of the invention is to provide a stereotactical instrument, which is compatible with available angiogram equipment and the like and which is easy to adjust.

According to the invention, these objects are achieved by means of an instrument as described above, which is characterised in that a non-resilient cranial strap is adjustably attached to the frame at opposite portions of the frame, that a bite block is movably attached to the frame and arranged to engage the upper teeth in the skull or the palate and that at least one pair of interacting fixing means provided with a scale are displaceably attached to the frame and arranged to engage, by means of support elements, the skin of the occipital bone in a non-invasive manner.

Further developments of the invention are defined in the subclaims.

Preferred embodiments of the invention will now be described by way of example, reference being made to the accompanying drawings in which

Fig. 1 is a top plan view of the non-invasive stereotactical instrument according to a preferred embodiment, where the cranial strap and the indication device have been removed for the sake of clarity;

Fig. 2 is a side view of the instrument in Fig. 1 with the cranial strap, as mounted on a patient;

Fig. 3 is a side view corresponding to the side view of Fig. 2 and illustrating the instrument as mounted on

the patient with a per se known box construction of a transparent material and integrated scales for indicating the position of the treatment area that is fixedly attached to the frame of the instrument;

Fig. 4 is a top plan view of the cranial strap as attached to a clamp provided with a scale;

Figs 5A and B are a front view and a side view respectively of a holder for a fixing means; and

Figs 6A and B are a side view and a cross-sectional view respectively of a fixing means, without its support element.

With reference now to Figs 1 and 2, the stereotactical instrument comprises a non-yielding frame 1 made of a suitable, light metal alloy, such as the frame described in the above-mentioned brochure. The frame 1 is closed and comprises, in the embodiment shown, two long sides 2 with grooves 3, each being provided with a scale 4. The rear short side 5 may also be provided with groove and scale, as appropriate. The frame 1 is intended to be lowered onto the patient's skull 6 and to be supported by the skull by means of a cranial strap 7 made of a suitable, non-resilient material, which preferably is radiolucent, such as a leather strap. In the embodiment shown, the cranial strap extends between the short sides 5 and 8 of the frame 1, but it could also, if required, extend between the long sides 2 or consist of several straps, should the location of the cranial strap impede the treatment which is to be performed.

The weight of the instrument is thus supported by the patient's skull 6 via the cranial strap 7, which is adjustably attached to the frame 1 by one end 9 of the cranial strap being fixedly attached to a clamp device 10, the two legs of which extend through two through holes 11 in the front short side 8 of the frame, said holes being symmetrically arranged about the longitudinal axis 24 (symmetry axis) of the frame. The clamp legs each have a scale as well as screw threads engaging a nut

means 12 on the underside of the frame 2, as shown in Figs 2, 3 and 4. The clamp device 10 is intended for fine adjustment of the frame and is normally not intended to be removed from the frame 1, as will be described in more detail below. The other end 13 of the cranial strap is provided with through holes 48, see Fig. 4, equidistantly spaced from each other and provided with identification marks for coarse adjustment of the cranial strap 7 in accordance with previous adjustments.

A plate 14 with a pad 15 made of a resilient material, for example rubber, on the inside is fixedly attached to the rear short side 5 of the frame and symmetrically arranged relative to the longitudinal axis 24 of the frame. The plate 14 protrudes almost perpendicularly to the plane of the frame from the outer surface of the short side 5 and has a locking means intended for the other, free end 13 of the cranial strap. The locking means comprises a pair of interacting pins 16 and 17, which are fixedly attached to the plate, one 16 above the other 17, the distance separating them corresponding to the distance between two not necessarily adjacent holes at the end 13 of the strap. The lower pin 17 is slanted downwards while the upper pin 16 protrudes at right angles from the plate 14. The design of the locking means allows the free end 13 of the cranial strap 7 to be quickly and safely attached, once the frame 1 has been lowered onto the skull 6, by arranging the relevant hole at the strap end 13 on the lower pin 17 in such manner that the hole slides upwards on this towards the plate 14. At the end of this motion, an upper hole in the strap end 13 can be arranged on the upper pin 16, whereby the lower pin 17 will prevent the cranial strap 7 from being removed from the plate 14, while the upper pin 16 will prevent the cranial strap from being rotated relative to the plate.

Alternatively, the other end 13 of the cranial strap 7 may be attached by means of a screw and with or without

a pin to the plate 14. The end 13 could also, if required, be attached directly to the short side 5 of the frame in the way described above. It is also conceivable that the other end 13 be fixedly mounted, although this would mean that the possibility of coarse adjustment of the cranial strap 7 would be lost and the versatility of the frame reduced.

On the opposite portion of the frame, i.e. on the front short side 8, a bite block 18 is movably attached to the frame 1. The bite block 18 is essentially Y-shaped, and its portion 19 arranged inside the frame is intended to be introduced into the patient's mouth and to engage the upper teeth in the skull 6 or the palate of the upper jaw. The portion 20 of the bite block protruding from the frame has a cutout 21 along the longitudinal axis of the bite block, said axis coinciding with the longitudinal axis 24 of the frame, and a scale 22, which is oriented parallel to said axis. The bite block 18 is displaceably and releasably arranged in a groove 23 on the underside of the frame, said groove being symmetrical with regard to the longitudinal axis 24 of the frame 1. The outer portion 20 of the bite block 18 is thus slideable in the groove 23 between the clamp holes 11 and adjustable by means of the scale 22. The bite block can be attached in the desired position along the axis 24 by means of a locking screw 25, which engages a threaded hole in the groove 23 in the lower portion of the short side 5 and which is arranged in the cutout 21. When the frame 1 is to be arranged on the patient, the bite block has preferably been removed from the frame, but once the cranial strap 7 is in place, the bite block is displaceably attached in the groove 23 by tightening the locking screw only partially, thus allowing the outer portion 20 to slide, by means of the cutout, on the inside (upper side) of the screw head.

It is of course possible, if so desired, to replace the cutout with a centre hole, through which the inner

portion 19 of the bite block may be pivoted away from the centre of the frame, so as to allow the frame to be put on, and then back to a position aligned along the axis 24. In this case, however, the possibility of adjustment is lost and the versatility of the frame reduced.

The bite block 18 preferably supports a tooth or palate casting (not shown) made of a resilient material on its upper side and corresponding with the patient's upper teeth or palate. Holes 26 in its inner portion 19 facilitate the fastening of the casting. Thus, different individuals having different skull sizes can use the frame 1; only the bite block with the casting is personal and has to accompany the patient. The bite block is intended to engage the upper teeth or the palate, since these constitute fixed reference points relative to the skull 6.

While the bite block 18 provides a front fixing point for the frame relative to the skull, and since the cranial strap 7 determines the vertical level of the frame 1 relative to the skull, at least two rear fixing points are required to allow the frame to be completely fixed to the skull. To this end, one pair of fixing means 27 and 28 are displaceably attached to the rear portion of the frame, preferably at or adjacent to the rear short side 5, said means being arranged to provide a non-invasive (bloodless) engagement with the occipital bone, below its edge, via the skin on the occipital bone. Since the occipital bone edge can be easily identified on most people, two safe fixing points are thus obtained.

Therefore, the fixing means 27 and 28 are preferably tilted upwards from the frame 1 generally towards the centre of the frame. A ball-and-socket joint is arranged at the inner end of each fixing means, said joint comprising a ball element 29 and a support element 30 which is pivotally supported on the ball element 29 and which is self-aligning with respect to the inclination of the corresponding engagement surface of the occipital bone of

the skull 6. The support element 30 is made of a suitable resilient material such as plastic. In Figs 2 and 3, the support element is shown as having the shape of a truncated cone, but any appropriate shape is possible. The fixing means 27 and 28 may have a smooth circumferential surface, in which case they are fixed with the aid of locking means on the frame. It is preferred, however, to provide the fixing means with external threads, which engage the matching threaded holes in the associated holders on the frame. The holders may be fixedly attached to the frame or consist of columns 31 which are displaceably arranged in grooves 32 transversely to the plane of the frame, i.e. the columns 31 are vertically adjustable relative to the frame. This allows the frame 1 to be vertically adjusted relative to the skull 6, and it can thus be positioned fairly low, substantially below ear level, which is of considerable importance since, as a result, the frame will not impede the work carried out with the aid of the treatment instruments.

Each column 31 is further provided with a scale in the longitudinal direction for repeatable alignment relative to the frame 1, and each fixing means 27 and 28 is also provided with at least one scale for this purpose. A segment of the screw-shaped fixing means may here have been milled or ground off, the resulting, essentially plane surface being provided with a scale, which is read against the column 31, see Figs 6A and B. Alternatively, a socket arrangement may be provided on the fixing means and the column, such as a micrometer, for adjusting the protrusion length of the fixing means from its holder.

As a supplement or alternative to the above-discussed fixing means 27 and 28, a second pair of fixing means 33 and 34 may be displaceably arranged on the frame 1 along each long side 2. The fixing means 33 and 34 engage, similarly to the fixing means 27 and 28 and preferably by means of threads, the associated holders 35 and 36 for adjusting the inserted length of the fixing

means 33 and 34 and have similar scale means. Each holder 35 and 36 has, for this purpose, more than one threaded through hole 37 and 38. The holders 35 and 36 are further adjustable along the respective scales 4 and run in grooves 3 in the frame 1. Each holder is locked in its alignment position in the groove 3 by means of an associated locking screw 39. The fixing means 33 and 34 also have a ball-and-socket joint at their inner end comprising a ball element 40 and a support element 41, which is pivotally supported on the ball element. The support element 41, which is preferably made of the same material as the support element 30, does not, however, have the shape of a truncated cone, but is bean-shaped with a substantially plane contact surface against the skull 6.

The above-mentioned second pair of fixing means 33 and 34 is intended to engage, in a non-invasive manner, the occipital bone behind each of the patient's ears via the skin on said bone. The fixing means can be repeatably adjusted by means of the above-mentioned scales on the fixing means and on the long sides of the frame 2 and a selected one of the holes 37 and 38 in each holder 35 and 36.

The spatial position of the area(s) which are to be subjected to (repeated) treatment is determined in per se known manner (by means of coordinate or solid angle system), cf. for example the brochure mentioned by way of introduction. In each treatment session, the frame 1 is lowered onto the patient's skull 6 and suspended from the cranial strap 7, which is coarse adjusted by means of the holes 48 in the end 13 of the strap in interaction with the pins 16 and 17, as described above, followed by a fine adjustment carried out with the aid of the clamp device 10 in interaction with the nuts 12 and in accordance with the identified setting values. The patient's personal bite block 18 with the tooth or palate casting is then aligned by means of the scale 22 and fixed in the direction of the longitudinal axis 24 of the frame

by tightening of the locking screw 25, the casting thus engaging the corresponding portion (teeth or palate) of the upper jaw. The final fixing of the frame 1 to the skull takes place by adjusting the position and protrusion length of the fixing means 27 and 28 and/or the fixing means 33 and 34 in accordance with that stated above and the identified values.

When the frame 1 has been fixed in the indicated position, a prior-art box construction 42, for instance, is placed on the frame 1, according to the preferred embodiment of the invention, and adjusted by means of the scale 4 and attached with the aid of fixing means 43. The box construction 42, which is made of a transparent and radiolucent material, comprises integrated scales 44 and 45 and reference lines 46 and 47 so as to allow identification of the treatment area. The marking device according to the above indicated US patent can be used advantageously also in this context.

The construction of the frame thus allows it to be easily and securely fixed to each patient's skull, knowing the setting values for each patient.

The stereotactical instrument according to the invention is thus supported without any discomfort by the patient during treatment and allows the patient to move relative to the treatment unit. It is also possible to attach the treating means of the treatment unit to the frame, for example by means of the device according to the indicated US patent. The instrument according to the invention may, of course, also be used to position the patient's skull relative to an operating table, examining table or the like and as holder for surgical instruments or the like.

The invention is not restricted to that described above and illustrated in the drawings, and may be modified in a number of ways within the scope of the appended claims.

CLAIMS

1. A non-invasive stereotactical instrument for identifying the spatial position of an area in a patient's skull (6) which is to be subjected to treatment, the position of the area being previously determined, for example by means of angiogram, PET or X-ray equipment, the instrument comprising a non-yielding frame (1), which is arranged to be supported by the patient's skull and to support an indicating device (42) and/or a treatment instrument, and fixing means (27, 28; 33, 34), which are displaceably attached to the frame and which are arranged to engage the skull for repeatable fixing of the instrument relative to the skull, c h a r a c t e r i s e d in that a non-resilient cranial strap (7) is adjustably attached to the frame (1) at opposite portions (5, 8) of the frame (1), that a bite block (18) is movably attached to the frame and arranged to engage the upper teeth in the skull or the palate and that at least one pair of interacting fixing means (27, 28) provided with a scale (49) are displaceably attached to the frame (1) and arranged to engage, by means of support elements (30), the skin of the occipital bone in a non-invasive manner.

2. An instrument as claimed in claim 1, c h a r a c t e r i s e d in that one end (9) of the cranial strap (7) is displaceably attached to the frame (1) adjacent to the bite block (18) and its other end (13) is releasably attached to the frame (1) between the fixing means (27, 28) of the occipital bone.

3. An instrument as claimed in claim 2, c h a r a c t e r i s e d in that one end (9) of the cranial strap is attached to a clamp device (10), which is provided with a scale and displaceably arranged in the frame (1) at an angle to the plane of the frame and which has at its ends screw-and-nut joints (12) engaging the under-

side of the frame for fine adjustment of the cranial strap (7).

4. An instrument as claimed in claim 2 or 3, c h a r a c t e r i s e d in that the other end (13) of the cranial strap can be releasably attached to a plate (14), which is fixedly attached to the frame (1) at an angle to the plane of the frame and which has a locking means (16, 17) for interactive engagement with position-defined through holes (48), arranged at the other end (13) of the cranial strap, for coarse adjustment of the cranial strap (7).

5. An instrument as claimed in claim 4, c h a r a c t e r i s e d in that the locking means comprises a pair of pins (16, 17), which are attached to the plate (14), one above the other, and which are arranged at a distance from each other corresponding to the distance between two holes at the other end (13) of the strap and of which the pin (17) closest to the frame is tilted towards the plane of the frame (1).

6. An instrument as claimed in any one of the preceding claims, c h a r a c t e r i s e d in that the bite block (18) is releasably attached to the frame (1), is displaceable in a direction parallel to the direction of the longitudinal axis (24) of the frame and interacts with a scale (22) for adjustment relative to the frame (1).

7. An instrument as claimed in claim 6, c h a r a c t e r i s e d in that the bite block (18) on its side facing the cranial strap (7) is provided with a tooth or palate casting which corresponds to the teeth and palate respectively of the patient's upper jaw.

8. An instrument as claimed in any one of the preceding claims, c h a r a c t e r i s e d in that the fixing means (27, 28) of the occipital bone are displaceably arranged on columns (31) interacting with a scale, said columns (31) being displaceably arranged in grooves (32) transversely of the plane of the frame, and that a

support element (30) is movably mounted on a ball element (29) at the inserted end of the respective fixing means (27, 28).

9. An instrument as claimed in any one of the preceding claims, c h a r a c t e r i s e d in that the fixing means (27, 28) of the occipital bone have external threads engaging matching threaded holes of the frame (1) or the columns (31).

10. An instrument as claimed in any one of the preceding claims, c h a r a c t e r i s e d in that two fixing means (33, 34) intended for non-invasive engagement with the skin on the skull (6) behind each of the patient's ears are displaceably arranged on the frame (1) parallel to its plane and along grooves (3) with a scale (4), the fixing means (33, 34) being engaged by means of threads with holders (35, 36), which are displaceably arranged in the groove (3), and having support elements (41), which are movably mounted on a ball element (40) at the inserted end of the respective fixing means (33, 34).

Application No: GB 0122999.6
Claims searched: 1-10

Examiner: Mark S Pritchard
Date of search: 8 May 2002

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T): A5R REYX

Int Cl (Ed.7): A61B 17/00 19/00

Other: WPI PAJ EPODOC

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X;Y	GB 2,213,066 A	THE INSTITUTE OF NEUROLOGY (QUEEN STREET), (Whole document)	1 at least
Y	US 4,617,925 A	LAITINEN (Figs. 1, 6 and 7 indicating use of scales)	1 at least
Y	US 4,350,159 A	GOUDA (Whole document, especially Fig. 1 and associated description, parts 34)	1 at least

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.